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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/630,414

07/30/2003

Zheng Z. Wu

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EXAMINER

HAGHIGHATIAN, MINA

ART UNIT

PAPER NUMBER

1616

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/630,414	Applicant(s) WU ET AL.	
	Examiner Mina Haghighatian	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The indicated allowability of claims 29-37 is withdrawn in view of the newly discovered reference(s). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The use of the trademark "SilcosteelTM process" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim 37 is indefinite for reciting a trademark (namely the "SilcosteelTM process" trademark). The process steps and limitations of the said process are not commonly known to all and also it is not permissible to claim a trademark.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 29-31, 34-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Lewis et al (US 20030089369 A1).

Lewis et al teach pressurized metered dose inhalers for delivering safe and stable formulations of active agents to a patient's pulmonary system. The formulations may comprise one or more active agents, typically a corticosteroid or bronchodilator, an HFA propellant and optionally a cosolvent and excipients. Specific active agents include corticosteroids (specifically 20-ketosteroids) such as budesonide, dexamethasone, mometasone, fluticasone, etc or any acceptable salt thereof. The inhaler has all or part of its internal surface coated with an inert material polymer, such as epoxy phenol. Containers with a glass interior have been used by Lewis, but are not the favorite for all corticosteroids (see [0030] to [0072]).

Lewis et al do not disclose vapor deposition or Silcosteel™ process of claims 34-35 and 37, however the said limitations are step methods related to method of making, and are not given weight in a formulation claim. In other words the end result, i.e. the formulation in a coated canister, is the same regardless of the specific process of coating the internal surface of the canister.

Claims 29-31, 34-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Lewis et al (US 20030066525 A1).

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Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al (US 20030066525 A1) in view of Ercoli et al (3,755,302).

Lewis et al, discussed above, lacks specific disclosure on using dexamethasone or betamethasone 17-valerate as suitable 20-ketosteroids.

Ercoli et al teach an improved process for the preparation of 17-monoesters of 17 α , 21-dihydroxy-20-keto-steroids which consists in carrying out the hydrolysis of corresponding 17, 21-cyclic orthoesters in a buffered aqueous-organic medium at a pH from about 4 to about 6 (see abstract and col. 1, lines 5-13). The said 20-keto-steroids include dexamethasone and betamethasone 17,21-methyl orthovalerate (see col. 3, lines 5-14). Examples 2 and 6 disclose a method of preparing betamethasone 17-valerate.

It would have been obvious to one of ordinary skill in the art given the general teachings of Lewis et al on stable corticosteroid solution formulations stored in a canister having its internal surfaces coated with an inert material to increase stability and shelf life, to have looked in the art for other specific species of corticosteroids such as 20-keto-steroids like dexamethasone and betamethasone with a reasonable expectations of successfully preparing stable and long lasting solution formulations comprising various steroids.

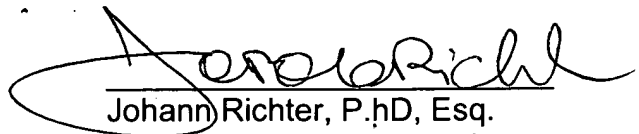
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MH

Mina Haghighatian
Patent Examiner
January 29, 2007


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